Trial Summary Report
Date:
Record Verification Date:

Official Title
A Phase II Study of Ziv-aflibercept in Combination With Capecitabine/Oxaliplatin (XELOX) Chemotherapy in the Front-Line Treatment of Patients With Metastatic Colorectal Cancer

Trial Identification	
NCI Trial Identifier	NCI-2014-00894
Lead Organization Identifier	CTRP_01_1776
ClinicalTrials.gov Identifier	NCT02079220

General Trial Details	
General Details	
Trial Type	Interventional
Lead Organization	NCI - Center for Cancer Research
Sponsor	National Cancer Institute
Responsible Party	No Data Available
Investigator	Diane Roulston
Investigator Title	
Investigator Affilliation	
Principal Investigator	Ajeet Gajra
Affilliation	
Collaborators	
Name	
DCP	
Wake Forest University at Lexington	
John Hopkins	
Status/Dates	
Current Trial Status	Withdrawn as of 2014-06-05
Trial Start Date	No Data Available
Primary Completion Date	No Data Available

Summary 4 Information	
Funding Category	Institutional
Funding Sponsor/Source	
No Data Available	
Anatomic Site Code	
Kidney	
Other Skin	

Regulatory Information	
Oversight Authority	
Country	Organization
No Data Available	
FDA Regulated Intervention?	Yes

Section 801?		Yes	
DMC Appointed?		Yes	
IND/IDE Study?		Yes	
IND/IDE			
Type	Grantor	Number	Holder Type
No Data Available			
Human Subject Safety			
Board Approval Status		No Data Available	
Board Approval Number		No Data Available	
Board		No Data Available	
Affiliation		No Data Available	

Trial Design	
Primary Purpose	Treatment
Secondary Purpose	N/A
Phase	II
Intervention Model	N/A
Number of Arms	
Masking	N/A
Allocation	N/A
Classification	N/A
Target Enrollment	

Trial Description
Brief Title
No Data Available
Brief Summary
No Data Available
Objectives
No Data Available
Detailed Description
No Data Available

Intervention(s)			
Type	Name	Alternate Name	Description
	CBP/beta-catenin Antagonist PRI-724		Given IV
	Bevacizumab		Correlative studies

Arm/Group(s)		
Arm Type	Label	Description
	Arm I (PRI-724, mFOLFOX6/bevacizumab)	Patients receive CBP/beta-catenin antagonist PRI-724 IV continuously on days 1-7, bevacizumab IV over 30 minutes
	Arm II	Patients receive

	(mFOLFOX6/bevacizumab)	bevacizumab, leucovorin calcium, oxaliplatin, and fluorouracil as in Arm I. Courses repeat every 14 days in the absence of disease progression or unacceptable toxicity.

Interventions	
Name	Description
CBP/beta-catenin Antagonist PRI-724	Given IV
Bevacizumab	Correlative studies

Eligibility Criteria	
Accepts Healthy Volunteers?	
Gender	
Minimum Age	
Maximum Age	
Inclusion Criteria	
Exclusion Criteria	

Disease/Condition

Primary Outcome Measures			
Title	Description	Time Frame	Safety Issue?

No Data Available

Secondary Outcome Measures			
Title	Description	Time Frame	Safety Issue?

No Data Available

Sub-groups Stratification Criteria	
Label	Description

Markers					
Marker Name	Evaluation Type	Assay Type	Biomarker Use	Biomarker Purpose	Specimen Type

Participating Sites				
Facility	Contact	Recruitment Status & Date(s)	Target Accrual	Investigator(s)
Coastal Carolina Radiation Oncology	Name: Email: leejj@upmc.edu	Withdrawn as of 2014-06-05		

	Phone: 412-648-6586 Ext:			

NCI Trial ID: NCI-2014-00894

Trial Overview
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Admin Data
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- Regulatory Information - Human Subject Safety
- Regulatory Information - IND/IDE
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- Trial Funding
- Participating Sites
- Collaborators
- Trial Related Documents
- NCI Specific Information

Scientific Data
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- Trial Description
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- Arms/Groups
- Eligibility Criteria
- Associated Trials
- Diseases/Conditions
- Data Table 4 Anatomic Sites
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- Sub-Groups Stratification
- Biomarkers

Complete

Trial Overview (NCI Trial ID: NCI-2014-00894)

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NCI ID: NCI-2014-00894
NCT ID: NCT02079220
Lead Organization Trial ID: CTRP_01_1776
Lead Organization: NCI - Center for Cancer Research
Submission Method: Registry
Amendment Number:
Amendment Date:

Principal Investigator: Ajeet Gajra
Clinical Research Category: Interventional
Last Submitter:
Last Submitter Organization:
Last Updated By:
Last Updated Date:

Information Source: Protocol
Current Trial Status: Withdrawn
Current Trial Status Date: 05-Jun-2014
Processing Status: Submitted
Checked Out for Admin. Use by:
Checked Out for Scientific. Use by:

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